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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,831	02/16/2001	Mikael Forsberg	10806-60A	3598

24256 7590 03/31/2003

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EXAMINER

SIPOS, JOHN

ART UNIT	PAPER NUMBER
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3721

DATE MAILED: 03/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/785,831

Applicant(s)

FORSBERG ET AL.

Examiner

John Sipos

Art Unit

3721

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### ***REJECTION ON PRIOR ART***

**Claims 21-27** are rejected under **35 U.S.C. ' 103(a)** as being unpatentable over the patent to Hjertman (5,435,076) in view Galy (5,148,450) or Meyer (4,491,876). The patent to Hjertman discloses the method of forming an ampoule by inserting a first piston 3 into the front chamber 5 of the barrel, filling the front chamber with a solution, performing a lyophilizing step, sealing the front opening of the barrel by inserting a sealer 11 into the opening, connecting and securing the sealer with the sleeve, filling the second chamber with material 6 and inserting a second piston 25 into the barrel. The patent does not disclose how the first piston is inserted into the barrel. The patents to Galy and Meyer show the insertion of a piston/movable plug 9 and 25, respectively, and the filling material through the same end of the ampoule since the diameter of the ampoules is constant. It would have been obvious to one of ordinary skilled in the art to insert the piston and material of Hjertman through the same front opening as shown by the secondary references since the diameter of the Hjertman piston is the same as the diameter of the ampoule.

### ***RESPONSE TO APPLICANT'S ARGUMENTS***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Note that Hjertman shows in Figure 3 an ampoule in which the barrel has a constant diameter which is the same as the diameter of the piston 3. Since the barrel is empty at the time of insertion of the piston, there are only two options for inserting the piston, i.e. through the front end or through the rear end. It would have been obvious to one of ordinary skilled in the art to eliminate the turning over steps of the ampoule and perform as many steps as possible from the same end of the ampoule by inserting both the filling material

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and the piston through the same front end. This is further shown to be the case by the secondary references that teach the same end insertion of the piston as the filling material.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

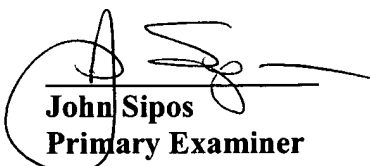
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to **Examiner John Sipos** at telephone number **(703) 308-1882**. The examiner can normally be reached from 6:30 AM to 4:00 PM Monday through Thursday.

The **FAX** number for Group 3700 of the Patent and Trademark Office is **(703) 305-3579**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Rinaldi Rada, can be reached at (703) 308-2187.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist whose telephone number is (703) 308-1148.

  
**John Sipos**  
**Primary Examiner**